DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 19, 2014

Mortara Instrument, Inc.
Ms. Amy Yang
Sr. Regulatory Affairs Engineer
7865 N. 86th Street
Milwaukee, WI 53224

Re: K141811
Trade/Device Name: Mortara Monitoring Waveform Viewer
Regulation Number: 21 CFR 870.1025
Regulation Name: Monitor, physiological, patient (with arrhythmia detection or alarms)
Regulatory Class: Class II
Product Code: MHX
Dated: October 2, 2014
Received: October 6, 2014

Dear Ms. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141811

Device Name
Monitoring Waveform Viewer

Indications for Use *(Describe)*

The Monitoring Waveform Viewer is indicated for use as follows:
The Monitoring Waveform Viewer is a software component utilized within another software application.

The Monitoring Waveform Viewer performs the following:
• Display of data generated by multi-parameter patient monitoring systems continuously producing waveforms and parameters.
• Display of reported alarm states produced by such monitoring systems.
• Display of static waveforms for review of existing data, with the possibility to activate a magnification tool. The magnification tool will enlarge the signal located under the magnification icon.
• Perform measurements with the support of a caliper tool (providing horizontal/time measurements and vertical/signal amplitude measurements). The caliper tool can be activated when the Monitoring Waveform Viewer displays still waveforms.
• Provide selected waveform episodes to the host application for printing or inclusion in the patient record.

The Monitoring Waveform Viewer:
• Is not a primary or secondary alarm device.
• Does not provide a user interface for acknowledging or silencing active alarms.
• Does not generate audible or visual (flashing) notifications of active alarms.

The Monitoring Waveform Viewer does not provide any support for implementing an application that is part of an alarm system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Abbreviated 510(k) Notification

510(k): Mortara Monitoring Waveform Viewer Summary
K141811

Submitter: **Date: November 18, 2014**

Amy Yang, Sr. Regulatory Affairs Engineer
Mortara Instrument, Inc.
7865 N. 86th Street
Milwaukee, WI 53224
FAX: (414) 354-4760
Phone: (414) 354-1600
Contact: Amy Yang (see above)

Trade Name: Mortara Monitoring Waveform Viewer
Common Name: Monitoring Waveform Viewer
Classification Name: Monitor, Physiological, Patient (with Arrhythmia Detection or Alarms)
Classification Description: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Classification Regulation: 21 CFR §870.1025
Product Code: MHX

Legally marketed devices to which S.E. is claimed:

Mortara Monitoring Waveform Viewer	Predicate 510(k) Number	Predicate Manufacturer / Model
Surveyor Central Station	K131929	Mortara Instrument, Inc. / Surveyor Central Station

Description:

The Monitoring Waveform Viewer is a software component that includes a system for reviewing snapshots of monitoring data and offers a measurement module with user controlled calipers and magnifier glass.

Medical device data or information system applications may utilize the Monitoring Waveform Viewer software component that includes a stand-alone executable module that functions as a host application. The Monitoring Waveform Viewer is organized as a drawing surface with three areas:

- a parameters area located at the bottom of the window,
- a parameter waveform area located at the right and
- a main waveform area.

The parameters area is dedicated to report the values of parameters not associated with displayed waveforms. The parameter waveform area is dedicated to report the values of parameters associated to the displayed waveforms.

The application supports several numerical parameters such as: ECG (electrocardiogram), ART (arterial pressure), PA (pulmonary artery invasive blood pressure), ICP (intracranial pressure), IABP (intra-aortic balloon pump pressure), RR (respiration rate), EtCO2 (end tidal carbon dioxide), SpO2 (oxygen saturation), etc.

The Monitoring Waveform Viewer receives data parameters and waveforms supplied from multi-parameter patient monitoring systems. The Monitoring Waveform Viewer is able to display alarm states by highlighting the corresponding parameter box. The Monitoring Waveform Viewer operating in near real time mode supports alarm priorities of High Priority, Medium Priority, and Low Priority.

Abbreviated 510(k) Notification

The Monitoring Waveform Viewer allows the user to right-click over any ECG lead or the ECG parameter box to activate a context menu for selecting the ECG gain and displayed leads. The user is able to select a list of active (with data) ECG leads received from the host application. It also allows the user to select gains of 5, 10, 20 and 40mm/mV. The Monitoring Waveform Viewer provides a caliper tool for performance amplitude and interval measurements on the displayed traces. The caliper can be placed anywhere on the waveform display area.

Further description and details concerning use of the Monitoring Waveform Viewer can be found in:

- Tab 2 Device Description, Monitoring Waveform Viewer Block Diagram
- Tab 12 Proposed Labeling documents, Monitoring Waveform Viewer product brochure, Monitoring Waveform Viewer User Manual.

Technology Comparison:

The Mortara Monitoring Waveform Viewer utilizes the same or similar technology for each parameter as utilized by the predicate devices.

Intended Use:

The Monitoring Waveform Viewer is a software component intended to be utilized within another software application. The software component can continuously receive and display data generated by multi-parameter patient monitoring systems in near real time, display reported alarm states, display static waveforms for review of existing data, and perform measurements with the support of a caliper tool.

The Monitoring Waveform Viewer software component is not intended to be used as an alarm device. The data and analysis provided by the Monitoring Waveform Viewer is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various conditions.

Indications for Use:

The Monitoring Waveform Viewer is indicated for use as follows:
The Monitoring Waveform Viewer is a software component utilized within another software application.

The Monitoring Waveform Viewer performs the following:

- Display of data generated by multi-parameter patient monitoring systems continuously producing waveforms and parameters.
- Display of reported alarm states produced by such monitoring systems.
- Display of static waveforms for review of existing data, with the possibility to activate a magnification tool. The magnification tool will enlarge the signal located under the magnification icon.
- Perform measurements with the support of a caliper tool (providing horizontal/time measurements and vertical/signal amplitude measurements). The caliper tool can be activated when the Monitoring Waveform Viewer displays still waveforms.
- Provide selected waveform episodes to the host application for printing or inclusion in the patient record.

The Monitoring Waveform Viewer:

- Is not a primary or secondary alarm device.
- Does not provide a user interface for acknowledging or silencing active alarms.
- Does not generate audible or visual (flashing) notifications of active alarms.

The Monitoring Waveform Viewer does not provide any support for implementing an application that is part of an alarm system.

Abbreviated 510(k) Notification

Performance Testing:
Sterilization Validation – The Mortara Monitoring Waveform Viewer is not sterilized or sterilizable, and therefore this section does not apply to the Waveform Viewer itself.

Shelf Life Testing – The Mortara Monitoring Waveform Viewer is not sterilized or sterilizable, and therefore this section does not apply to the Waveform Viewer itself.

Biocompatibility Testing – The Mortara Monitoring Waveform Viewer is software only, and therefore this section does not apply to the Waveform Viewer itself.

Software Testing – Software for the Mortara Monitoring Waveform Viewer was designed and developed according to a robust software development process, and was rigorously verified and validated. Test results indicated that the Mortara Monitoring Waveform Viewer complies with its predetermined specification.

Electrical Safety – The Mortara Monitoring Waveform Viewer is software only, and therefore this section does not apply to the Waveform Viewer itself.

Electromagnetic Compatibility Testing – The Mortara Monitoring Waveform Viewer is software only, and therefore this section does not apply to the Waveform Viewer itself.

Performance Testing – Bench – The Mortara Monitoring Waveform Viewer was tested in accordance with internal requirements and procedures, and test results indicated that the device complies with the predetermined requirements. This testing includes performance and functional.

Performance Testing – Animal – Animal performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the Mortara Monitoring Waveform Viewer.

Performance Testing – Clinical - Clinical performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the Mortara Monitoring Waveform Viewer.

Conclusion – The results of these activities demonstrate that the Mortara Monitoring Waveform Viewer is as safe, as effective, and performs as well as or better than the predicate device.